REMARKS

In the Office Action dated April 4, 2007, claims 2 and 6 were rejected under 35 U.S.C. §112, first paragraph as failing to comply with the enablement requirement. The Examiner stated claims 2 and 6 lack enablement because the Examiner stated Equation (2) at page 3 of the present specification shows compliance "as a function of itself multiplied by a volume to the power (1-b)".

In response, this paragraph at page 3, as well as the preceding paragraph, have been amended to make clear that, as set forth at the left side of original Equation (2), compliance is designated as "C(V)," and the term C in Equation (2) is a constant. In order to avoid confusion with regard to Equation (1), Equation (1) has been amended consistent with original Equation (2) to designate compliance as C(V).

Applicants submit that since the Examiner was able to determine that Equation (2) could not possibly be referencing compliance as being defined in terms of itself, these changes do not constitute new matter and are consistent with the context in which Equation (2) appears in the original application.

Claims 2 and 6 have been amended consistent with this discussion as well. Claims 2 and 6 are therefore submitted to in full compliance with all provisions of Section 112, first paragraph.

Claims 1, 3-5, 7, 8 and 12 were rejected under 35 U.S.C. §102(b) as being anticipated by Yamada. Claim 11 was rejected under 35 U.S.C. §103(a) as being unpatentable over Yamada in view of Banner et al.

In response, each of independent claims 1 and 5 has been amended to make clear that the respiratory gas is at a pressure that is either a constant pressure or a

pressure that conforms to a pre-set pressure profile. Independent claims 1 and 5 have also been amended to state that resistance and compliance are determined from the pressure and the measured flow, as well as to state that the stress index value has a magnitude that indicates whether the compliance is increasing or decreasing during inspiration.

For the reasons discussed below, in view of these changes to the independent claims, Applicants submit that neither claim 1 nor claim 5 is anticipated by the Yamada reference.

The Yamada reference corresponds to European Application 0 521 515, which was cited as Reference AM in the Information Disclosure Statement filed May 7, 2004, and which was extensively discussed in the present specification in the discussion beginning at the bottom of page 2. As explained at page 4 of the present specification, and as mathematically demonstrated at that location, the method disclosed in the Yamada reference is unsuitable for use with a gas flow that exhibits a constant pressure, or a pressure that conforms to a pre-set pressure profile, as now set forth in independent claims 1 and 5. As explained in the present specification, the Yamada reference discloses a method and an apparatus for establishing a stress indicator during constant flow inspiration, i.e., volume-controlled ventilation. As disclosed in the Yamada reference, the profile of a pressure-time relationship is determined, that occurs during the supply of a constant gas flow. The convexity/concavity of the pressure-time curve, which serves as an indicator of pulmonary stress (i.e. decreasing or increasing compliance), is determined by fitting or conforming the curve to a generally arbitrary power equation or polynomial equation. The equation is taught by Yamada to include a constant, which are the

constants V and gamma in the examples given in the Yamada reference. The constant serves as a determinant for the shape of the function profile, and by conforming the equation to the measured pressure-time curve, the constant can be determined. By obtaining a constant that is indicative of the change in the compliance of the patient's lungs, a ventilator can be controlled dependent on that value.

Although this procedure is suitable under the conditions described in the Yamada reference, the present inventors have had the insight to recognize that this approach cannot be used during ventilation wherein breathing gas at a constant pressure, or conforming to a pre-set pressure profile, is supplied to the subject, because under that condition there will be no pressure-time curve that can be obtained from measured values. Although the Yamada reference suggests that similar curves can be obtained by determining or calculating the lung pressure during pressure-controlled ventilation, such curves do not contain any useable information regarding pulmonary mechanics of the ventilated subject, and thus cannot be used to determine a stress index indicator by the curve conforming technique disclosed in the Yamada reference.

By contrast, the approach disclosed and claimed in the present application makes use of mathematical equations that describe pulmonary mechanics of the subject, and parameters are identified therein that are indicative of the shape of the function profile.

There is no teaching or suggestion in the Yamada reference to employ any method or apparatus that does not make use of a pressure-time relationship, and in fact the Yamada technique cannot even be used if such a pressure-time relationship

is not present, as is the case in the conditions that are now explicitly set forth in independent claims 1 and 5, these conditions being a constant pressure or a pressure that conforms to a pre-set pressure profile.

Therefore, neither independent claim 1 or independent claim 5 is anticipated by the Yamada reference, nor are any of the claims depending therefrom.

As to the rejection under 35 U.S.C. §103(a) based on Yamada and Banner et al, the above discussion is also applicable. Even if the Examiner's statements concerning the Banner et al reference are correct, for the reasons discussed above modifying the Yamada reference in accordance with those teachings still would not result in the subject matter of claim 11, which embodies the subject matter of independent claim 5 therein.

Applicants note with appreciation that claims 2 and 6 were stated to be allowable if rewritten to overcome the rejections under Section 112, first paragraph as well as being rewritten in independent form, and that claims 9 and 10 also were stated to be allowable if rewritten in independent form. In view of Applicants' belief that amended independent claims 1 and 5 are patentable over the art of record, those dependents claims have been retained in dependent form at this time.

All claims of the application are therefore submitted to be in condition for allowance, and early reconsideration of the application is respectfully requested.

Submitted by,

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